

## **DETAILED ACTION**

### ***Claim Interpretation***

1. Regarding the method limitations recited in claim(s) 40-53, 67-74, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

As such, Applicant has not set forth convincing evidence, made of record that structurally distinguishes the instant claimed product from the prior art of record.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**4. Claims 40-51 and 53 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pitt (USP 5,037,656).**

Regarding claims 40-51 and 53, Pitt discloses a composite porous membrane (title/abstract) having an amino functionalized substrate (C2/L41-45 - Nylon will inherently provide primary chain end and secondary chain link type amine groups on the surface of the nylon substrate) wherein there is a pore size of the membrane of 0.001-15 microns (C3/L9-13 - note also that nylon is a biocompatible substrate) and a monomer is deposited via graft polymerization (C3/L9-12) wherein a free radical polymerizable monomer, a polymerization initiator are contacted with the substrate (C3/L58-66) using monomers including acrylic acid (C4/L12-28) and polymerization initiators including 4,4-azobis-(4-cyanovaleric acid) (C4/L29-45).

**5. Claim 52 is rejected under 35 U.S.C. 103(a) as obvious over Pitt (USP 5,037,656).**

Regarding claim 52 Pitt discloses all of the claim limitations as set forth above. Pitt does not explicitly set forth the use of dimethylaminopropyl acrylamide. However, Pitt does in fact set forth the use of monomers of acrylic and methacrylates (C4/L23-28) and further sets forth the use of 2-N,N-dimethylaminopropyl methacrylate (C4/L24-25) and further sets forth the use of like materials (C4/L23-18-28) It would have been obvious to one of ordinary skill in the art at the time of the invention to use dimethylamionpropyl acrylamide instead of one of the methacrylates taught in Pitt as the art recognizes the equivalence of the compounds and the selection of any known equivalent would have been within the level of ordinary skill in the art.

**6. Claims 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitt et al. (USP 5,037,656), and in view of Bell et al. (USP 6,774,102).**

Regarding claims 67-69 Pitt discloses all of the claim limitations as set forth above. Pitt does not explicitly set forth the use of the separating material as for endotoxin removal from blood or affinity adsorption applications.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollow fiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Pitt and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Pitt as a hollow fiber or bead for removal of endotoxins via affinity adsorption as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claim 70, Pitt discloses all of the claim limitations as set forth above. Pitt does not explicitly set forth the use of the separating material as beads in a separating column.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45). Bell et al. further discloses packing the beads into polycarbonate columns for blood purification (C7/L15-40).

Pitt and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Pitt as a bead for removal of endotoxins via affinity adsorption in a separation column as taught by Bell et al. for the purpose of improved blood endotoxin removal.

**7. Claim 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitt et al. (USP 5,037,656), and further in view of Duggins (USP 4,668,399).**

Regarding claims 71 and 72, Pitt discloses all of the claim limitations as set forth above. Pitt does not explicitly disclose a separating cartridge with a tube, and potting hollow fibers in it.

Duggins discloses a hollow fiber plasmapheresis module in figures 1-3 comprising a hollow fiber membrane module (14) which is shown in figure 3 as a tube with hollow fibers in it. Furthermore, it is well known that in hollow fiber membrane modules, the fibers are potted to secure them.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the membrane type of Pitt in a hollow fiber membrane module as taught by Duggins for the purpose of plasmapheresis.

**8. Claims 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitt et al. (USP 5,037,656), and further in view of Steuck (4,618,533).**

Regarding claims 73-74, Pitt discloses all of the claim limitations as set forth above.

Steuck discloses a composite porous membrane formed from a porous polymeric membrane (abstract) which is exposed to a monomer and an initiator (C3/L45-66) wherein hydrophilizing copolymers are utilized as the substrate (C2/L60-C3/L11).

Pitt and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of polymer radical grafting.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the polymer membrane of Pitt such that the substrate is formed from a hydrophilic copolymer as taught by Bell et al. for the purpose of improving the separation capacity and increasing the water affinity.

Regarding claim 75, Pitt as modified does not explicitly set forth the use of PVP or PEO. However, Steuck does in fact set forth the use of related materials. Accordingly, PVP and PEO have art recognized equivalent function and properties such that they have become recognized as similar equivalents. It would have been obvious to one of ordinary skill in the art at the time of the invention to use PVP or PEO as hydrophilizing polymers as the art recognizes the equivalence of the two compounds and the selection of any known equivalent would have been within the level of ordinary skill in the art.

### ***Response to Arguments***

9. Applicant's arguments filed 8/23/2011 with respect to the method of making claims (54 and 80 and subsequent dependant claims) were found persuasive. The prior art of record is silent as to the use of the sequential steps as claimed wherein the radical initiator is contacted to and covalently coupled to the amine groups followed by

the radical initiator contacted substrate being further contacted with the monomer.

According, claims 54 and 80 and subsequent dependant claims are allowed.

Applicant's arguments filed 8/23/2011 with respect to the instant disclosed product claims (40 and subsequent dependant claims including method of using the product) were not found to be persuasive.

It is first noted that the previously cited Drumheller reference was not per se part of the obviousness grounds of rejection but rather cited as an evidentiary reference to establish something as known in the art and/or equivalent. Accordingly, Drumheller was never being combined or included into either of Horl and/or Pitt.

Applicant continues to argue the product-by-process claim 40. Applicant does not argue with evidence that the structure of the product is patentably distinct, just that the method of making the product is. The Examiner concedes that neither Pitt nor Horl set forth the instant claimed method of making. However, claim 40 is drawn towards a product. The Examiner considers that at minimum Pitt sets forth the product of claim 40. As set forth above, Pitt discloses a graft polymerized monomer polymerized onto a nylon substrate using a radical initiator. While the exact manner of polymerization initiation may not be identical, the chemicals used are considered identical and/or equivalent. Accordingly, the product of Pitt anticipates and/or obviates the product of claim 40. Applicant has not set forth convincing evidence of the record which structurally differentiates the product of claim 40 from that of Pitt. The Examiner notes that on 7/28/2010 there was an evidentiary declaration filed comparing products of Storr to products of Horl. There was no comparison made to the product of Pitt or to product

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of Horl/Pitt. Additionally, an unexplained discrepancy between claim scope and the experimental results exists. Storr provides for a virtually unlimited reaction time (>16 hrs) while Horl is performed at a 3 hr reaction time. Since reaction time is unclaimed, these results are not compelling. Additionally, there is no comparison between Storr and Pitt. The previously submitted results further appear to indicate that the criticality lies in the reaction time and not other specific process steps.

10. Applicant's arguments with respect to claims 40-53 and 67-75 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

11. Claims 54-66 and 76-96 allowed.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Primary Examiner, Art Unit 1774

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